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10/677,420	10/02/2003	Thomas C. Kienzle III	132385 (14088US02)	8453
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/677,420	Applicant(s) KIENZLE ET AL.
	Examiner CHRISTIAN SEVILLA	Art Unit 3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 05 January 2011.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-24 is/are pending in the application.
 4a) Of the above claim(s) 13-24 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-12 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 5, 2011 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-24 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 3, 7, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (US 6190395) in view of Vilsmeier, *et al.* (US

2003/0078565; "Vilsmeier" herein) and further in view of Ferre, *et al.* (US 6175756; "Ferre" herein).

Regarding claims 1, 2, and 11, Williams discloses a system (10) for tracking the position of an instrument (32) relative to an area of interest (14). The system comprises an instrument (32). The system comprises an instrument guide (44) mounted to the instrument, the instrument guide carrying a first localizer (34) proximate the instrument, the first localizer being movable relative to the instrument. The system comprises a fixator (16), the fixator configured to be attached to an area of interest, the fixator carrying a second localizer (20) proximate the area of interest, the first and second localizers being movable in order that the first and second localizers are in communication such that the position of one of the localizers is known relative to the position of the other of the first and second localizers. The position of the first localizer relative to the instrument may be adjusted {e.g., via clamping band 46}. The system comprises a computer (28).

Williams fails to disclose the second localizer is movable with respect to the fixator; and the position of the second localizer relative to the fixator may be adjusted.

Vilsmeier discloses an aligning device 10 on a fixing device 1 wherein the aligning device comprises a screw 10a that permits turning a reference star 11 about the longitudinal axis of the fixing device and the aligning device further comprises a screw 10b that permits turning the reference start 11 around an axis with is perpendicular to a middle axis of the fixing device 1 (para. [0041]). By using the aligning

device 10, the reference star can be positioned for good detection of markers attached to the reference star 11 (para. [0041]).

It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified Williams in view of Vilsmeier to include the second localizer is movable with respect to the fixator. Doing so would have permitted further positioning the second localizer for better detection of markers attached to the second localizer.

Williams further fails to disclose one of the first and second localizers directly communicates with the other of the first and second localizers; and the first localizer is an electromagnetic receiver and the second localizer is an electromagnetic transmitter, the transmitter and receiver being connected to the computer to analyze the communication therebetween to calculate the position of the receiver relative to the transmitter.

Ferre discloses a position tracking and imaging system wherein a headset 12 may be employed in systems based on the triangulation of signals where a reference unit 36 includes one or more signal transmitters and/or one or more signal receivers; in such a triangulation system, position detection is achieved by comparing certain characteristics of one transmitted signal with those of a second transmitted signal to determine the relative distances traveled; and the signals may be electromagnetic (e.g., radio, laser light or light emitting diodes) (col. 4, line 59 - col. 4, line 67).

It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified Williams in view of Ferre to include one of the first and

second localizers directly communicates with the other of the first and second localizers. Doing so would have provided additional signal transmitters and/or signal receivers for employing systems based on triangulation of signals, thereby providing additional means of determining position of a surgical instrument relative to a target region.

Regarding claim 3, Williams further discloses an imaging device (CAT scanner; col. 4, lines 21-27) that takes images (image data set; col. 4, lines 21-27) of the area of interest, the images being stored on a computer system (28; col. 4, lines 33-41) capable of calculating the position of the second localizer on the images and calculates the position of the first localizer relative to the images.

Regarding claim 7, Williams further discloses the instrument is a surgical drill guide and the area of interest is an area of a patient's body, the first and second localizers being connected to a computer (28) carrying images of the area of interest, the computer analyzing the communication between the first and second localizers to calculate the position of the instrument relative to said images.

Regarding claim 8, Williams discloses the first and second localizers are light emitting diodes {col. 5, lines 3; col. 4, line 19}.

Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Vilsmeier and Ferre, as above, and further in view of Schenk, et al. (US 5895389; "Schenk" herein).

Regarding claim 4, Williams discloses the instrument guide include a localizer assembly (34, 50). The localizer assembly carries the first localizer (34).

Williams fails to disclose the instrument guide includes a handle assembly connected to the localizer assembly at concentric collars, the collars receiving the instrument along a longitudinal axis, the collars being rotatable relative to each other such that the first localizer is rotatable about the longitudinal axis relative to the instrument and handle assembly.

Schenk discloses a collapsible drilling guide wherein a plunger (30) telescopically slides in a sleeve (10) {col. 4, lines 41-44}; a handle (24) secured to the sleeve by two pins (26) {col. 4, lines 32-34}; and scale (44) graduates the outside of the plunger (30) to indicate the amount by which the guide has been collapsed {col. 5, lines 16-17}.

It would have been obvious to a person having ordinary skill in the art to have modified Williams in view of Schenk to construct the instrument guide includes a handle assembly connected to the localizer assembly at concentric collars, the collars receiving the instrument along a longitudinal axis, the collars being rotatable relative to each other such that the first localizer is rotatable about the longitudinal axis relative to the instrument and handle assembly. Doing so would have permitted a surgeon to more precisely determine drilling depth, thereby preventing the drill from extending too deeply into bone.

Regarding claim 10, Williams discloses the instrument guide include a localizer assembly (34, 50). The localizer assembly carries the first localizer (34).

Williams fails to disclose the instrument guide includes a handle assembly connected to a first collar and the localizer assembly carrying the first localizer and being connected to a second collar, the first and second collars being connected and

concentrically aligned and receiving the instrument, the first and second collars being configured to move relative to each other about the instrument.

Schenk discloses a collapsible drilling guide wherein a plunger (30) telescopically slides in a sleeve (10) {col. 4, lines 41-44}; a handle (24) secured to the sleeve by two pins (26) {col. 4, lines 32-34}; and scale (44) graduates the outside of the plunger (30) to indicate the amount by which the guide has been collapsed {col. 5, lines 16-17}.

It would have been obvious to a person having ordinary skill in the art to have modified Williams in view of Schenk to construct the instrument guide so that it includes a handle assembly connected to a first collar and a localizer assembly carrying the first localizer and being connected to a second collar, the first and second collars being connected and concentrically aligned and receiving the instrument, the first and second collars being configured to move relative to each other about the instrument. Doing so would have permitted a surgeon to more precisely determine drilling depth, thereby preventing the drill from extending too deeply into bone.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Vilsmeier and Ferre, as above, and further in view of Haynes (US 2238870).

Regarding claim 5, Williams fails to disclose the fixator includes a block receiving screws in channels therein, the second localizer being connected to the block and the screws being inserted into the area of interest, the block being adjustable along the

screws in order to adjust the position of the second localizer relative to the area of interest.

Haynes discloses a base member (3) with screws (4) that pass through spaced openings (5) in the base member {Fig. 2}.

It would have been obvious to a person having ordinary skill in the art to have modified Williams in view of Haynes in order that the fixator includes a block receiving screws in channels therein, the second localizer being connected to the block and the screws being inserted into the area of interest, the block being adjustable along the screws in order to adjust the position of the second localizer relative to the area of interest. Doing so would have permitted more secure affixation of the fixator and the second localizer to bone, thereby further preventing unwanted shifting of the second localizer.

Regarding claim 6, Williams fails to disclose the fixator includes a block connected to the area of interest, the fixator further including first and second clamps and a post, the first and second clamps being adjustably connected to the block and the post being adjustably connected to the first and second clamps, the post receiving the second localizer such that the second localizer is adjustable relative to the block along the first and second clamps and the post.

Haynes discloses a base member (3) with screws (4) that pass through spaced openings (5) in the base member {Fig. 2}; a post (9); first and second clamps (18, 19); the first and second clamps being adjustably connected to the block {member 8 forms part of a ball and socket connection; p. 1, right col., lines 18-20; Fig. 3}.

It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified Williams in view of Haynes in order that the fixator includes a block connected to the area of interest, the fixator further including first and second clamps and a post, the first and second clamps being adjustably connected to the block and the post being adjustably connected to the first and second clamps, the post receiving the second localizer such that the second localizer is adjustable relative to the block along the first and second clamps and the post. Doing so would have permitted immobilizing the ends of bone fragments for the purpose of reducing a bone fracture, thus adapting the device for use in a wider range of surgical applications.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Vilsmeier and Ferre, as above, and further in view of Davison (US 4710075).

Williams fails to disclose fixator includes a post, the post having a shaft with a spring and dowel mechanism thereon, the second localizer receiving the shaft such that the dowel engages the second localizer and the spring is loaded between the second localizer and the post to secure the second localizer to the post.

Davison discloses a medical device in which a first member (26) is slidably disposed over a second member (16) {Figs. 1 & 4; col. 4, lines 31-36}. A coil spring (60) is disposed in a cavity (40) such that the spring biases a plunger (44). Ridges (48) on the plunger are selectively received into grooves (20) in the second member.

It would have been obvious to a person having ordinary skill in the art to have modified Williams in view of Davison in order that the fixator includes a post, the post

having a shaft with a spring and dowel mechanism thereon, the second localizer receiving the shaft such that the dowel engages the second localizer and the spring is loaded between the second localizer and the post to secure the second localizer to the post. Doing so would have increased the level of separability between the fixator and the second localizer, thereby facilitating quicker replacement of the second localizer for the purpose of repair or improvement.

Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Vilsmeier, Ferre, and further in view of Sati (US 2002/005679; "Sati" herein).

Regarding claim 12, Williams discloses a system (10) for tracking the position of an instrument (32) relative to an area of interest (14). The system comprises an instrument (32). The system comprises an instrument guide (44) mounted to the instrument, the instrument guide carrying a first localizer (34) proximate the instrument, the first localizer being movable relative to the instrument. The system comprises a fixator (16), the fixator configured to be attached to an area of interest, the fixator carrying a second localizer (20) proximate the area of interest, the first and second localizers being movable in order that the first and second localizers are in communication such that the position of one of the localizers is known relative to the position of the other of the first and second localizers. The position of the first localizer relative to the instrument may be adjusted {e.g., via clamping band 26}.

Williams fails to disclose the second localizer is movable with respect to the fixator; and the position of the second localizer relative to the fixator may be adjusted.

Vilsmeier discloses an aligning device 10 on a fixing device 1 wherein the aligning device comprises a screw 10a that permits turning a reference star 11 about the longitudinal axis of the fixing device and the aligning device further comprises a screw 10b that permits turning the reference start 11 around an axis with is perpendicular to a middle axis of the fixing device 1 (para. [0041]). By using the aligning device 10, the reference star can be positioned for good detection of markers attached to the reference star 11 (para. [0041]).

It would have been obvious to have modified Williams in view of Vilsmeier to include the second localizer is movable with respect to the fixator. Doing so would have permitted turning the second localizer relative to the fixator to permit good detection of the second localizer relative to a detector.

Williams further fails to disclose one of the first and second localizers directly communicates with the other of the first and second localizers.

Ferre discloses a position tracking and imaging system wherein a headset 12 may be employed in systems based on the triangulation of signals where a reference unit 36 includes one or more signal transmitters and/or one or more signal receivers; in such a triangulation system, position detection is achieved by comparing certain characteristics of one transmitted signal with those of a second transmitted signal to determine the relative distances traveled; and the signals may be electromagnetic (e.g., radio, laser light or light emitting diodes) (col. 4, line 59 - col. 4, line 67).

It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified Williams in view of Ferre to include one of the first and

second localizers directly communicates with the other of the first and second localizers. Doing so would have provided additional signal transmitters and/or signal receivers for employing systems based on triangulation of signals, thereby providing additional means of determining position of a surgical instrument relative to a target region.

Williams further fails to disclose the first and second localizers may be adjusted relative to a third localizer to optimize communication between the three localizers.

Sati discloses a surgical system and method wherein objects to be tracked comprise markers which can be configured to emit, receive, or reflect energy (para. [0010], lines 6-8).

It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified Williams in view of Sati to include the first and second localizers may be adjusted relative to a third localizer to optimize communication between the three localizers. Doing so would have permitted tracking additional surgical instruments, thereby facilitating a wider range of surgical procedures.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN SEVILLA whose telephone number is (571)270-5621. The examiner can normally be reached on Monday through Thursday, 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THOMAS C. BARRETT can be reached on (571)272-4746. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTIAN SEVILLA/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775